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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,269	02/17/2004	Keith M. Grispo	L-F / 223	2232

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EXAMINER	
GILBERT, ANDREW M	
ART UNIT	**PAPER NUMBER**
3767	

MAIL DATE	DELIVERY MODE
12/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,269	GRISPO, KEITH M.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2006*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-17 and 40-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-17 and 40-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/5/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 3/5/2007.

2. In the reply, the Applicant amended claims 11-13, 15; cancelled claims 1-10, 18-39; and added new claims 40-56.

3. Thus, claims 1-17, 40-56 are pending for examination.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1—17, 40-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Medrad, Inc., "Stellant CT Injection System", Operation Manual Catalog #SOM 700 EN, 2003, 88 pages - hereafter, "Stellant".

6. Stellant discloses a dual head injector (pg 11, 16) comprising: a first head (pg 16) configured to receive a first syringe; a second head (pg 16) configured to receive a second syringe; and, Y-tubing coupling (pg 30) the first and second syringe; a control circuit programmatically controlling the dual head injector to fill said first and second syringes and inject fluid into a patient from said first and second syringes (pgs 35-52),

the control circuit programmed to control said injector through a purge routine (34-36) to automatically purge substantially all of the air from the first and second syringes and the Y tubing and configured with a separate function (pg 35-52) to programmatically control said injector to inject fluid into a patient; the Y-tubing including a first section (pg 30) coupled to the first head, wherein in the execution of the purge routine said first head first purges air from the first syringe and the first section of tubing (pg 30, 34-36); the Y-tubing including a second section (pg 30) coupled to the second head, a connector (pg 30) coupled to the first and second sections, and third section (pg 30) coupled to the connector, wherein in the execution of the purge routine said second head next purges air from the second syringe, the second section of tubing, the connector and the third section of tubing (pg 30, 34-36); wherein the first syringe is a pre-filled syringe of contrast media (pg 5, 16, 29, 31; wherein either syringe may contain contrast media or saline); wherein the second syringe is a pre-filled syringe of saline solution (pg 5, 16, 29, 31; wherein either syringe may contain contrast media or saline); wherein one of the first and second syringes contains a contrast media (pg 5, 16, 29, 31; wherein either syringe may contain contrast media or saline); wherein one of the first and second syringes contains a saline solution (pg 5, 16, 29, 31; wherein either syringe may contain contrast media or saline); wherein said first head is enclosed within a first housing and said second head is enclosed within a second housing (pg 16); wherein said purge routine comprises one or more steps requiring user interaction (pg 34-36); wherein said purge routine comprises a first step of purging air from said first syringe and obtaining confirmation thereof from a user (pg 34-36); wherein said purge routine comprises a

second step of purging air from said second syringe and obtaining confirmation thereof from a user (pg 34-36); wherein said purge routine comprises a step of enabling the injector (pg 34-36), the control circuit configured to programmatically control said injector to inject fluid into a patient only when enabled (pg 34-52).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 11-17, 40-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cornacchia et al (5472403) in view of Stellant. Cornacchia et al discloses a dual head injector comprising: a first head (36) configured to receive a first syringe (2); a second head (38) configured to receive a second syringe (4); and, Y-tubing coupling (22) the first and second syringe; the dual head injector configured to automatically purge substantially all of the air from the first and second syringes and the Y tubing (Summary; col 3, lns 60-65); the Y-tubing including a first section coupled to the first head, wherein the first head first purges air from the first syringe and the first section of tubing; the Y-tubing including a second section coupled to the second head, a connector coupled to the first and second sections, and third section coupled to the connector, wherein the second head next purges air from the second syringe, the second section of tubing, the connector and the third section of tubing (Fig 1, Summary,

col 2, lns 50-col 3, lns 65); wherein the first syringe is a pre- filled syringe of contrast media (col 2, lns 53-55; wherein the Examiner notes that radionuclide is a type of contrast agent – see Summary) and wherein the second syringe includes a saline solution (col 2, lns 63-65).

9. However, Comacchia et al does not disclose the control circuit programmed to control said injector through a purge routine to automatically purge substantially all of the air from the first and second syringes and the Y tubing and configured with a separate function to programmatically control said injector to inject fluid into a patient and wherein said purge routine comprises one or more steps requiring user interaction; wherein said purge routine comprises a first step of purging air from said first syringe and obtaining confirmation thereof from a user; wherein said purge routine comprises a second step of purging air from said second syringe and obtaining confirmation thereof from a user; wherein said purge routine comprises a step of enabling the injector, the control circuit configured to programmatically control said injector to inject fluid into a patient only when enabled.

10. Stellant teaches that it is known to have the control circuit programmed to control said injector through a purge routine (pg 34-36) to automatically purge substantially all of the air from the first and second syringes and the Y tubing and configured with a separate function (pg 36-52) to programmatically control said injector to inject fluid into a patient and wherein said purge routine comprises one or more steps requiring user interaction (pg 34-36); wherein said purge routine comprises a first step of purging air from said first syringe and obtaining confirmation thereof from a user (pg 34-36);

wherein said purge routine comprises a second step of purging air from said second syringe and obtaining confirmation thereof from a user (pg 34-36); wherein said purge routine comprises a step of enabling the injector (pg 34-36), the control circuit configured to programmatically control said injector to inject fluid into a patient only when enabled (pg 34-52) for the purpose of expelling all trapped air from the syringes, connectors, and tubing to minimize air embolization risks. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the control programming as taught by Comacchia et al with the purge routine as taught by Stellant for the purpose of expelling all trapped air from the syringes, connectors, and tubing to minimize air embolization risks.

11. Claims 11-17, 40-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cornacchia et al (5472403) in view of Wilson et al (5573515). Cornacchia et al discloses the invention substantially as claimed.

12. However, Comacchia et al does not disclose the control circuit programmed to control said injector through a purge routine to automatically purge substantially all of the air from the first and second syringes and the Y tubing and configured with a separate function to programmatically control said injector to inject fluid into a patient and wherein said purge routine comprises one or more steps requiring user interaction; wherein said purge routine comprises a first step of purging air from said first syringe and obtaining confirmation thereof from a user; wherein said purge routine comprises a second step of purging air from said second syringe and obtaining confirmation thereof

from a user; wherein said purge routine comprises a step of enabling the injector, the control circuit configured to programmatically control said injector to inject fluid into a patient only when enabled.

13. Wilson et al teaches that it is known to have the control circuit programmed to control said injector through a purge routine (Summary; Figs 2B, 7B, 8B; col 6, lns 7-28, col 8, lns 60-col 9, lns 5; col 9, lns 52-61; col 10, lns 11-30; col 13, lns 12-30) to automatically purge substantially all of the air from the first and second syringes and the Y tubing and configured with a separate function (see Patient Injection Operation) to programmatically control said injector to inject fluid into a patient and wherein said purge routine comprises one or more steps requiring user interaction (col 9, lns 52-61, col 10, lns 11-30; wherein it is clear that the user has control over the initiation of the purge routine, and the initiation of the patient injection operation); wherein said purge routine comprises a first step of purging air from said first syringe and obtaining confirmation thereof from a user (col 9, lns 52-61, col 10, lns 11-30; wherein it is clear that the user has control over the initiation of the purge routine, and the initiation of the patient injection operation); wherein said purge routine comprises a step of enabling the injector (col 9, lns 52-61, col 10, lns 11-30; wherein it is clear that the user has control over the initiation of the purge routine, and the initiation of the patient injection operation), the control circuit configured to programmatically control said injector to inject fluid into a patient only when enabled (col 9, lns 52-61, col 10, lns 11-30; wherein it is clear that the user has control over the initiation of the purge routine, and the initiation of the patient injection operation) for the purpose of expelling air from the

components prior to patient injection. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the control programming as taught by Comacchia et al with the purge routine as taught by Wilson et al for the purpose of expelling air from the components prior to injection.

14. Claim 11-17, 40-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuda (6917828) in view of Stellant. Fukada discloses a dual head injector comprising: a first head (3a) configured to receive a first syringe (1a); a second head (3b) configured to receive a second syringe (1b); and, Y-tubing coupling (2; col 1, lns 20-25) the first and second syringe; the dual head injector configured to automatically purge substantially all of the air from the first and second syringes and the Y tubing (Summary); the Y-tubing including a first section coupled to the first head, wherein the first head first purges air from the first syringe and the first section of tubing; the Y-tubing including a second section coupled to the second head, a connector coupled to the first and second sections, and third section coupled to the connector, wherein the second head next purges air from the second syringe, the second section of tubing, the connector and the third section of tubing (Fig 1-9, Summary; wherein the Examiner notes the device is fully capable of performing the Applicant's claimed limitations – see discussion above in Claim Notes); wherein the first syringe is a pre- filled syringe of contrast media (Fig 9; 1a) and wherein the second syringe includes a saline solution (Fig 9, 1b).

15. However, Fukuda does not disclose the control circuit programmed to control said injector through a purge routine to automatically purge substantially all of the air from the first and second syringes and the Y tubing and configured with a separate function to programmatically control said injector to inject fluid into a patient and wherein said purge routine comprises one or more steps requiring user interaction; wherein said purge routine comprises a first step of purging air from said first syringe and obtaining confirmation thereof from a user; wherein said purge routine comprises a second step of purging air from said second syringe and obtaining confirmation thereof from a user; wherein said purge routine comprises a step of enabling the injector, the control circuit configured to programmatically control said injector to inject fluid into a patient only when enabled.

16. Stellant teaches that it is known to have the control circuit programmed to control said injector through a purge routine (pg 34-36) to automatically purge substantially all of the air from the first and second syringes and the Y tubing and configured with a separate function (pg 36-52) to programmatically control said injector to inject fluid into a patient and wherein said purge routine comprises one or more steps requiring user interaction (pg 34-36); wherein said purge routine comprises a first step of purging air from said first syringe and obtaining confirmation thereof from a user (pg 34-36); wherein said purge routine comprises a second step of purging air from said second syringe and obtaining confirmation thereof from a user (pg 34-36); wherein said purge routine comprises a step of enabling the injector (pg 34-36), the control circuit configured to programmatically control said injector to inject fluid into a patient only

when enabled (pg 34-52) for the purpose of expelling all trapped air from the syringes, connectors, and tubing to minimize air embolization risks. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the control programming as taught by Fukuda with the purge routine as taught by Stellant for the purpose of expelling all trapped air from the syringes, connectors, and tubing to minimize air embolization risks.

17. Claim 11-17, 40-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuda (6917828) in view of Wilson et al. Fukuda discloses the invention substantially as claimed.

18. However, Fukuda does not disclose the control circuit programmed to control said injector through a purge routine to automatically purge substantially all of the air from the first and second syringes and the Y tubing and configured with a separate function to programmatically control said injector to inject fluid into a patient and wherein said purge routine comprises one or more steps requiring user interaction; wherein said purge routine comprises a first step of purging air from said first syringe and obtaining confirmation thereof from a user; wherein said purge routine comprises a second step of purging air from said second syringe and obtaining confirmation thereof from a user; wherein said purge routine comprises a step of enabling the injector, the control circuit configured to programmatically control said injector to inject fluid into a patient only when enabled.

19. Wilson et al teaches that it is known to have the control circuit programmed to control said injector through a purge routine (Summary; Figs 2B, 7B, 8B; col 6, lns 7-28, col 8, lns 60-col 9, lns 5; col 9, lns 52-61; col 10, lns 11-30; col 13, lns 12-30) to automatically purge substantially all of the air from the first and second syringes and the Y tubing and configured with a separate function (see Patient Injection Operation) to programmatically control said injector to inject fluid into a patient and wherein said purge routine comprises one or more steps requiring user interaction (col 9, lns 52-61, col 10, lns 11-30; wherein it is clear that the user has control over the initiation of the purge routine, and the initiation of the patient injection operation); wherein said purge routine comprises a first step of purging air from said first syringe and obtaining confirmation thereof from a user (col 9, lns 52-61, col 10, lns 11-30; wherein it is clear that the user has control over the initiation of the purge routine, and the initiation of the patient injection operation); wherein said purge routine comprises a step of enabling the injector (col 9, lns 52-61, col 10, lns 11-30; wherein it is clear that the user has control over the initiation of the purge routine, and the initiation of the patient injection operation), the control circuit configured to programmatically control said injector to inject fluid into a patient only when enabled (col 9, lns 52-61, col 10, lns 11-30; wherein it is clear that the user has control over the initiation of the purge routine, and the initiation of the patient injection operation) for the purpose of expelling air from the components prior to patient injection. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the control

programming as taught by Fukuda with the purge routine as taught by Wilson et al for the purpose of expelling air from the components prior to injection.

Response to Arguments

20. Applicant's arguments with respect to claims 11-17 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571)

272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

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